

**BIOMEGA COLD PAIN THERAPY- menthol, unspecified form and camphor (synthetic) cream**

**Concept Laboratories, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**BioMega™**

**Cold Pain Therapy Cream**

***Drug Facts***

<b><i>Active ingredient</i></b>	<b><i>Purpose</i></b>
Menthol 12%	Topical Analgesic
Camphor 6%	Topical Analgesic

**Uses**

for the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains

**Warnings**

**For external use only.**

- This is not a face cream. Do not apply to the face.
- If sensitive skin, ask a health professional before use. Do not use if past allergic reaction to menthol or camphor.
- Do not apply to wounds or damaged, broken, sunburned, chapped or irritated skin.
- Do not bandage tightly.
- Do not apply within 1 hour before or after bath, shower, hot tub, sauna or vigorous exercise. Warm water, perspiration or open pores can intensify the impact of this product, burning sensation or cold sensation.
- Do not use with heating pad, hot water bottle or other source of heat. Doing so can increase risk of serious burns.

**When using this product**

- Do not get into eyes and avoid contact with other mucous membranes. If contact occurs or if pain, discomfort or skin redness occurs, continually rinse with cool water and seek medical help.

**Discontinue use and consult a doctor if** condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days. Stop using and get immediate medical attention if experience burning, pain, swelling, skin irritation or blistering of the skin.

**If pregnant, breast-feeding or any medical conditions exist,** ask a health professional before use.

**Keep out of reach of children and pets.** If swallowed, get medical help or contact a Poison Control Center right away. If inhaled, remove to fresh air. Get emergency medical help if difficulty breathing, swelling of face, lips, tongue or throat, or hives.

**Directions**

- Rotate pump's spout counter-clockwise slightly to unlock; clockwise to lock.
- Before using on children under 18 years of age consult a physician.
- Apply sparingly to affected area not more than 4 times daily. However, for first use, apply to small skin area to test for sensitivity or skin reaction.
- Gently massage into the skin until fully absorbed.
- Wash hands with soap and water thoroughly after each application to avoid spreading to the eyes or other sensitive mucous membranes.

**WARNING****FLAMMABLE PRODUCT!**

Store in a cool well ventilated area away from heat. Keep away from sparks or open flame.

**Inactive ingredients**

Water (Aqua), SD Alcohol 40-B, Aloe Barbadensis Leaf Juice, Propylene Glycol, Mentha Piperita (Peppermint) Oil, Arnica Montana Flower Extract, Carbomer, Acrylates Copolymer, Corn Starch Modified, Linum Usitatissimum (Linseed) Seed Oil, Euterpe Oleracea Fruit Oil, PPG-2 Hydroxyethyl Cocamide, Rosmarinus Officinalis (Rosemary) Leaf Oil, Hydrolyzed Corn Starch, Lauryl Laurate, Methyl Diisopropyl Propionamide, Ethyl Mentane Carboxamide, Menthyl Lactate, Hydrated Silica, Zea Mays (Corn) Starch, Hydrolyzed Corn Starch Octenylsuccinate.

**Questions or comments?**

Call toll-free 1-877-630-9788 or visit us at [www.biomegarxp.com](http://www.biomegarxp.com)

Manufactured by: Concept Laboratories, Inc. Chicago, IL 60642

**PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label****BIOMEGA™*****Triple Strength*****COLD PAIN THERAPY Cream**

*with* Cooling Menthol &  
Camphor

- Omegas 3,6 & 9
- With Natural Ingredients
- Ice Pearls™ Technology  
For Hours Of Therapy

8 FL OZ (237mL)

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Topical Analgesic  
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### Questions or comments?

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Manufactured for: SCI  
Plano, TX 75024  
Manufactured by: Concept Laboratories, Inc.  
Chicago, IL 60642

ITEM #1654455

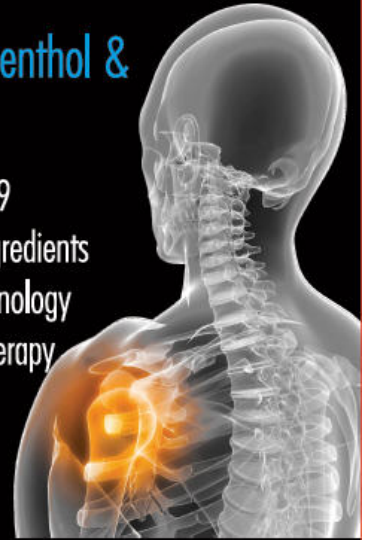


# BIOMEGA™

## Triple Strength COLD PAIN THERAPY Cream

with Cooling Menthol & Camphor

- Omegas 3,6 & 9
  - With Natural Ingredients
  - Ice Pearls™ Technology
- For Hours Of Therapy



Paraben-free topical analgesic for  
Strains • Sprains • Muscle Pain • Tension

8 FL OZ (237mL)

## BIOMEGA COLD PAIN THERAPY

menthol, unspecified form and camphor (synthetic) cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64058-344
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.12 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.06 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ALCOHOL (UNII: 3K9958V90M)	
STARCH, CORN (UNII: O8232NY3SJ)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
LINSEED OIL (UNII: 84XB4DV00W)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
ACAI OIL (UNII: Z0W6766A2W)	
PPG-2 HYDROXYETHYL COCAMIDE (UNII: 34N07GUJ3X)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
LAURYL LAURATE (UNII: GPW77G0937)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-344-68	234 g in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	01/07/2016	

**Labeler** - Concept Laboratories, Inc. (962282612)

### Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-344)

Revised: 2/2016

Concept Laboratories, Inc.